REMARKS

The final Office Action dated August 29, 2003, has been carefully considered. Claims 1-29 are pending in the present application. Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 1, 3, 8, 10-12, 14, 19, 21, And 22 Are Patentable Over U.S. Patent 5,545,208 To Wolff *et al.* ("Wolff") In View Of U.S. Patent No. 6,558,733 B1 To Hossainy *et al.* ("Hossainy)

Claims 1, 3, 8, 10-12, 14, 19, 21, and 22 have been rejected under 35 U.S.C. § 103(a) as allegedly being anticipated by Wolff in view of Hossainy. This rejection is respectfully traversed.

Independent claims 1 and 12 are directed to an expandable stent for implantation in a patient comprising a tubular metal body having open ends and a sidewall structure having openings therein, wherein the sidewall structure is prefabricated. A coating is disposed on a surface of the prefabricated sidewall structure, wherein the coating comprises a hydrophobic biostable elastomeric material and a biologically active material. Claim 1 also recites that the coating continuously conforms to the structure in a manner that preserves the openings. Claim 12 also recites that the openings are substantially free of webbing. Claims 3, 8, 10, and 11 depend from claim 1, and thus also include all the recitations of claim 1. Claims 14, 19, 21, and 22 depend from claim 12, and thus also include all the recitations of claim 12. As explained in the present application, the tubular body "is formed of an open braid of fine single or polyfilament metal wire." (Specification, page 3, lines 32-33). In addition, "[t]he coating process enables the material to adherently conform to and cover the entire surface of the filaments of the open structure of the stent in a manner such that the open lattice nature of the structure of the braid or other pattern is preserved, in the coated device." (Specification, page 4, lines 18-21).

As discussed in the Amendment filed on June 13, 2003, and as acknowledged by the Examiner in the present Office Action, Wolff does not disclose or suggest a sidewall ~~structure that is prefabricated and accordingly a coating comprising a hydrophobic biostable elastomeric material and a biologically~~ active material that is disposed on the surface of the prefabricated sidewall structure.

In contrast, Wolff discloses a stent that includes drug eluting filaments that are braided together to form a stent. (Col. 7, lines 7-23). The "filaments could be impregnated with a drug and biodegradably elute." (Col. 7, lines 20-21). A single filament could be braided into the stent or varying numbers of strands that are drug-eluting could be braided into a filament that forms the stent. (Col. 7, lines 7-23). Thus, in Wolff the filaments include a drug or are coated with a drug before the filaments are woven together. Wolff discloses that "[i]n all cases, the prostheses of [Wolff's] invention require the presence of an elutable drug compounded to the prosthesis itself." (Col. 2, lines 12-14. (Emphasis added)). Thus, the drug coating is not applied to a prefabricated stent, but incorporated into the filaments themselves before the filaments are formed into a stent.

Wolff discloses that "[w]ith conventional metal stents, the invention requires a drug-carrying coating overlying at least a portion of the metal." (Col. 2, line 14-16). However, as explained above, Wolff does not disclose or suggest that the coating is disposed on a prefabricated sidewall structure of a metal stent. Instead, Wolff discloses a coating on individual filaments that are then woven together. Wolff discloses that the "exterior surface of the metal filaments 22 would include a coating 14 with a drug-eluting polymer." (Col. 6, lines 60-61). Wolff also states that Fig. 13 shows a filament that is formed with a metal core 16 and a coating 14. (Col. 7, lines 33-34). But Wolff does not disclose or suggest that the filaments are formed into a sidewall structure and then coated with a biologically active material and a polymer. In fact, Wolff teaches away from a coating on a prefabricated sidewall structure by disclosing individual filaments that are coated and then braided or woven or bonded together. (Col. 7, lines 7-36.)

Also, in referring to Figure 3B, Wolff expressly states that Figure 3B shows that "the *filament* 12 may be made from one or several layers of polymer." (Col. 9, lines 23-25). (Emphasis added). Wolff does not even use the term "coating" in discussing Figure 3B. Hence, this figure does not show a coating for the prosthesis but a filament or wire-like portion which forms a part of the prosthesis, *i.e.*, a substrate upon which a coating can be placed. Accordingly, items 14 and 15 shown in Figure 3B are *not* layers of a coating disposed on a prefabricated sidewall of a stent but are instead layers of the filament used to form a prosthesis. Hence, instead of comprising a coating on a prefabricated sidewall of a stent, items 14 and 15 in Figure 3B describe a filament used to form the prosthesis. In contrast, Applicants' invention is directed to a stent having a prefabricated sidewall structure that is covered by a coating of a hydrophobic biostable elastomeric material and a biologically active material.

Hossainy does not remedy the deficiencies of Wolff. Hossainy does not disclose or suggest "a coating disposed on a surface of said prefabricated sidewall structure [having openings therein], said coating comprising a hydrophobic biostable elastomeric material and a biologically active material." Hossainy also does not disclose or suggest a coating that "continuously conforms to said structure in a manner that preserves said openings" as recited in claim 1, or that the "openings are substantially free of webbing" as recited in claim 12.

In contrast, Hossainy discloses a prosthesis, such as a stent, having a body structure that has "one or more micropatterned microdepots formed therein." (Col. 2, lines 35-42). Figs. 4a and 4b of Hossainy show such depots 30 on a stent 10. Hossainy states that the "depots have an open end, a closed end, and a diameter and a depth that is less than the thickness of the body structure of the prosthesis." (Col. 2, lines 42-44). Hossainy further discloses that "various drugs or therapeutic substances may be loaded into the depots." (Col. 7, lines 54-55). For instance, Hossainy discloses that the "depots 30 are used to carry a variety of substances including . . . polymers impregnated with therapeutic substances." (Col. 4, lines 38-40). Hossainy discloses that "[c]ontrolling the size of the opening [of the depot] that contacts the surface of a tissue also controls the rate at which a therapeutic substance is released once the stent 10 is implanted at the desired location of treatment." (Col. 6, lines 55-58). Hossainy does not disclose or suggest that the therapeutic substance can be deposited anywhere other than into the depots that are formed in the stent.

Because Hossainy's therapeutic substance is only loaded into one or more *depots* on the stent, such therapeutic substance does not adherently conform to and cover the entire surface of the filaments of a prefabricated open structure of the stent in a manner such that the open lattice nature of the structure of the braid or other pattern is preserved in the coated device, as does the coating used in the present invention. (*See* Specification, page 4, lines 18-21). Thus, Hossainy does not disclose or suggest the his therapeutic substance *continuously conforms* to the sidewall structure in a manner that preserves the openings therein as recited in claim 1 or that such substance is applied so that the openings in the sidewall structure are substantially free of webbing as recited in claim 12. Therefore, Hossainy does not disclose or suggest a coating comprising a hydrophobic biostable elastomeric material and a biologically active material on the surface of a prefabricated sidewall structure that has openings therein as presently claimed. In fact, by only applying a substance into depots in the stent, Hossainy teaches away from applying a *coating* on the surface of a sidewall structure as presently claimed.

Moreover, there is no motivation to combine the teachings of Wolff and Hossainy to obtain the present invention where Wolff teaches away from a prefabricated sidewall structure having openings therein, and Hossainy teaches away from a coating on the surface of a prefabricated sidewall structure.

Accordingly, Wolff and Hossainy, either individually or in combination, do not disclose or suggest a coating that includes a hydrophobic biostable elastomeric material and a biologically active material that is disposed on a surface of a prefabricated sidewall structure as required by the present claims. Thus, it is believed that claims 1, 3, 8, 10-12, 14, 19, and 21-22 are patentable over Wolff and Hossainy. Reconsideration and withdrawal of this rejection, and allowance of claims 1, 3, 8, 10-12, 14, 19, 21, and 22 are respectfully requested.

B. Claims 2, 4, 5, 13, And 15-16 Are Patentable Over Wolff In View Of Hossainy And Further In View of U.S. Patent No. 5,900,246 To Lambert ("Lambert")

Claims 2, 4, 5, 13, and 15-16 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wolff in view of Hossainy and further in view of Lambert. This rejection is respectfully traversed.

Claims 2, 4, and 5 depend from claim 1 which was shown above to be patentable over Wolff and Hosssainy. Claims 13, 15, and 16 depend from claim 12 which was also shown above to be patentable over Wolff and Hossainy. As stated above, Wolff and Hossainy do not disclose or suggest a coating that includes a hydrophobic biostable elastomeric material and a biologically active material that is disposed on a prefabricated sidewall structure as required by the present claims. Also, there is no motivation to combine the teachings of Wolff and Hossainy to obtain the present invention because Wolff teaches away from a prefabricated sidewall structure having openings therein, and Hossainy teaches away from a coating on the surface of a prefabricated sidewall structure.

In addition, Wolff and Hossainy also do not disclose or suggest a thickness of a coating as recited in claims 2, 5, 13, and 16. In addition, with respect to claims 4 and 15, Wolff and Hossainy also do not disclose or suggest a coating that is applied to the surface of the sidewall structure by spraying. As explained above, both references do not even disclose or suggest a coating on a prefabricated sidewall structure as presently claimed. Thus, for these additional reasons, it is believed that claims 2, 4, 5, 13, and 15-16 are patentable over Wolff and Hossainy.

Like Hossainy, Lambert also does not remedy the deficiencies of Wolff. Lambert discloses a stent coated with a polyurethane having a drug incorporated therein. In its examples, Lambert uses nitinol stents or stainless steel coils. However, Lambert does not teach an expandable stent or a stent having a sidewall structure having openings therein. Since Lambert does not disclose or suggest a sidewall structure having openings therein, Lambert fails to disclose or suggest a coated stent having a coating that continuously conforms to the structure in a manner that preserves the openings or a coated stent having openings substantially free of webbing as recited in the present claims. Moreover, there is no motivation to combine the teachings of Wolff and Lambert where Wolff teaches away from coating a prefabricated sidewall structure having openings therein, and Lambert does not even disclose or suggest a sidewall structure having openings therein.

Thus, Wolff, Hossainy and Lambert, either individually or in combination, do not disclose or suggest a coating disposed on a prefabricated sidewall structure having openings therein as recited in the present claims. Moreover, there is no motivation to combine the teachings of Wolff, Hossainy, and Lambert to obtain the present invention where Wolff teaches away from coating a prefabricated sidewall structure having openings therein, Hossainy teaches away from a coating disposed on the surface of a sidwall structure, and Lambert does not even disclose or suggest a sidewall structure having openings therein.

Accordingly, it is believed that claims 2, 4, 5, 13, 15, and 16 are patentable over Wolff in view of Hossainy and further in view of Lambert. Reconsideration and withdrawal of this rejection, and allowance of claims 2, 4, 5, 13, and 15-16 are respectfully requested.

C. Claims 6, 7, 9, 17-18, And 20 Are Patentable Over Wolff In View Of Hossainy And Further In View Of U.S. Patent No. 5,464,650 to Berg *et al.* ("Berg")

Claims 6, 7, 9, 17-18, and 20 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wolff in view of Hossainy and further in view of Berg. This rejection is respectfully traversed.

Claims 6, 7, and 9 depend from claim 1, and claims 17, 18, and 20 depend from claim 12. Claims 1 and 12 were shown above to be patentable over Wolff and Hossainy, and thus the dependent claims are also believed to be patentable over Wolff and Hossainy. As stated above, there is no motivation to combine the teachings of Wolff and Hossainy to obtain the present invention where Wolff teaches away from a prefabricated sidewall structure having openings therein, and Hossainy teaches away from a coating on the surface of a prefabricated

sidewall structure. With respect to claims 6, 7, 17, and 18, Wolff does not disclose or suggest applying a coating to a stent or a prefabricated sidewall structure, and Hossainy does not even disclose or suggest a coating as discussed above. In addition, Wolff does not disclose or suggest the metals recited in claims 9 and 20. Thus, it is believed that claims 6, 7, 9, 17, 18, and 20 are patentable over Wolff and Hossainy for these additional reasons.

Like Hossainy, Berg also does not remedy the deficiencies of Wolff. Unlike the present invention, Berg does not describe or suggest a coated stent having openings therein, wherein the coating continuously conforms to the structure in a manner that preserves the openings or wherein the openings are substantially free of webbing as recited in the present claims. Berg is completely silent as to whether the openings in its stent contains a webbing of coating material. Furthermore, one of ordinary skill in the art would not be motivated to combine Berg with Wolff where Wolff teaches away from coating a pre-fabricated sidewall structure.

One of ordinary skill in the art would also not be motivated to combine the teachings of Wolff, Hossainy, and Berg, particularly where Wolff teaches away from coating a pre-fabricated sidewall structure and Hossainy teaches away from a coating on the surface of a sidewall structure.

Accordingly, it is believed that claims 6, 7, 9, 17-18, and 20 are patentable over Wolff in view of Hossainy and further in view of Berg. Reconsideration and withdrawal of this rejection, and allowance of claims 6, 7, 9, 17-18, and 20 are respectfully requested.

D. Claims 23-29 Are Patentable Over Lambert In View of Hossainy

Claims 23-29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lambert in view of Hossainy. This rejection is respectfully traversed.

Claim 23 recites a "self-expandable stent for implantation in a patient comprising a tubular metal body having open ends and a sidewall structure having openings therein and a coating . . . on a surface of said sidewall structure, . . . wherein said coating continuously conforms to said structure in a manner that preserves said openings." Claims 24-29 depend from claim 23 and thus also include those elements.

As discussed above, Lambert does not disclose or suggest an expandable stent or a stent having a prefabricated sidewall structure having openings therein. Since Lambert does not disclose or suggest a sidewall structure having openings therein, Lambert also fails to

disclose or suggest a coated stent having a coating that continuously conforms to the structure in a manner that preserves the openings as recited in the present claims.

Hossainy does not remedy the deficiencies of Lambert. Hossainy does not disclose or suggest a coating on the surface of a prefabricated sidewall structure having openings therein as discussed above. Thus, Hossainy also does not disclose or suggest a coating having a particular thickness or a coating that continuously conforms to the structure in a manner that preserves the openings as recited in the present claims. Moreover, one of ordinary skill in the art would not be motivated to combine the teachings of Lambert and Hossainy to obtain the present invention where both references fail to disclose or suggest a coated stent having a coating that continuously conforms to the structure in a manner that preserves the openings as recited in the present claims.

Thus, it is believed that claims 23-29 are patentable over Lambert in view of Hossainy. Reconsideration and withdrawal of this rejection, and allowance of claims 23-29 are respectfully requested.

II. CONCLUSION

As all rejections are believed to be overcome, all claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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